REMARKS

Claims 1-9 are pending in the current application and have been rejected. Claims 1 and 2 have been amended herein and new claims 10-27 have been added. The new claims are fully supported by the specification and claim previously unclaimed subject matter. Applicants respectfully submit that no new matter has been added. In addition, paragraph [0023] has been amended herein to correct a typographical error. Reconsideration and withdrawal of the rejections are respectfully requested in light of the above amendments and following remarks.

The Examiner has rejected claims 1-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicant regards as the invention. Specifically, the Examiner has stated that it is unclear what constitutes "substantially lower pressure" and a "conventional syringe." Claim 1 has been amended herein to recite that the ratio of the diameter of the chamber to the passageway is such that the fluid pressure in the chamber is less than 40 psi when a 10 lb force is applied to the plunger rod. Since the unclear terms have been deleted from claim 1, it is respectfully submitted that the 35 U.S.C. 112, second paragraph rejection has been overcome and should be withdrawn.

The Examiner has rejected claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Howe (5,242,405). The Examiner states that Howe discloses, *inter alia*, a syringe (20), a rubber stopper (39), an elongated plunger rod (40), a tip cap (44) and a flush solution (43), wherein the chamber contains no more than 3.5 mL of solution. The Examiner similarly relies on Talonn et al. (5,395,339) as disclosing all of the same features as disclosed in Howe. The Examiner further asserts that while Howe and Talonn do not disclose that the chamber has a diameter of 13.5mm and a length of 57mm, these dimensions are deemed to be matters of design choice. The Examiner points to Applicants' statements in paragraph [0027] on page 6 of the specification, "in which the Applicant discloses that a wide variety of dimensions could be used and the recited dimensions are only the preferred embodiment."

To clarify, Applicants statement at paragraph [0027] reads as follows:

> Although a wide variety of *chamber lengths* are within the purview of the *present invention*, the preferred embodiment has a chamber length C of no more than about 57mm (2.25 inches) with a chamber length of no more than about 44.5mm (1.75 inches) to 38.1mm (1.5 inches) being desirable for many applications.
> (Emphasis added).

The Applicants have not stated that a wide variety of dimensions could be used, but rather that a wide variety of chamber lengths are within the purview of the present invention. This is by no means an admission that any of a "wide variety of dimensions" could be used. Turning to the claims, which recite what the Applicants deem to be their invention, and specifically to claim 1, which has been amended herein, the ratio of the diameter of the chamber to the diameter of the passageway must be such that the fluid pressure is less than 40 psi when a 10 pound force is applied to the plunger rod. In addition to this

feature, claim 1 further requires that length of the chamber cannot be longer than 57mm. The prior art does not disclose these features and Applicants submit that these features are not merely a matter of design choice.

The present invention, due to these claim features, present several advantages over the prior art. As discussed in the specification at paragraph [0034] a major advantage of the present invention is that the fluid pressure will be about only one-third of the fluid pressure of a prior art 3ml syringe (such as the syringes disclosed in Howe and Talonn). The use of a larger diameter, but shorter length syringe, which has not been available before for I.V. flushing applications, is advantageous in that the pressures are reduced making it easier for the user to detect a clot and less likely that the catheter will be damaged due to high pressure, which was problematic in the past. (*See* paragraph [0034], page 8). Moreover, in the present invention, a lower fluid pressure than a prior art 10ml syringe is achieved but with a smaller sized syringe. This results in less waste of the flush solution, since in the past a user would have required a 10ml syringe. Yet another advantage of the present invention is that because it is smaller in size, it takes up less room in a sharps collector or medical waste container. Applicants respectfully submit that these advantages make it clear that the claim features of claim 1, with respect to chamber length, chamber diameter and the total fluid pressure in the chamber are not merely design choices. Since the prior art fails to disclose each of the limitations of claim 1, and Applicants submit that the features of claim 1 are not merely design choices, but provide the invention with many advantages over the prior art, it is requested that the 35 U.S.C. 103(a) rejection be withdrawn with respect to claim 1. In addition, since claims 2-9 depend either directly or indirectly from claim 1, it is respectfully requested that the 35 U.S.C. 103(a) rejection be withdrawn with respect to these claims as well.

The Examiner has further rejected claims 1-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,361,524. Applicants submit herewith a timely filed terminal disclaimer to overcome this rejection.

New Claims

As stated above, new claims 10-27 have been added to the present application and Applicants submit that no new matter has been added. Support for new claims 10-13 may be found throughout the specification. (*See e.g.*, Paragraphs [0027]-[0029] and [0035]-[0037]). Since claims 10-13 depend directly or indirectly from claim 1, they include all of the features of claim 1, in addition to other novel features. Therefore, it is believed that new claims 10-13 are allowable for at least the reasons set forth above with respect to claim 1.

New claim sets 14-19 and 20-25 each recite a method of using the syringe assembly similar to that recited in claim 1. Support for these method claims can be found throughout the specification. (*See, e.g*, Paragraphs [0033]-[0034]). Independent claims 14 and 20 require that the inside diameter of the

syringe assembly is at least 13.5mm and that when a 10 pound force is applied to the plunger rod, the fluid pressure in the chamber is less than 40psi. As discussed above, the cited prior art fails to disclose these limitations. As such, it is respectfully submitted that new claims 14-25 are allowable.

Claim set 25-27 claim a kit which includes two syringe assemblies, one of those syringe assemblies being similar to the syringe assembly claimed in claim 1. Support for these new claims may be found throughout the specification. (*See, e.g.,* Paragraph [0041] and Fig. 9). It is respectfully submitted that the prior art fails to disclose each of the features of the kit claims, for at least the reasons set forth above, with respect to the features of the first syringe assembly of claim 25. Thus it is believed that new claims 25-27 are patentable.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (201) 847-6797 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 02-1666 therefor.

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Respectfully submitted,

By: /Jeanne P. Lukasavage Reg No 45172/

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, New Jersey 07417
201-847-6797

Jeanne P. Lukasavage
Registration No. 45,172

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